## DETAILED ACTION

### *Prosecution History Summary*

- Claims 12 and 15 are cancelled.
- Claims 1-11, 13-14, and 16-28 are pending.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim1-6, 8-10, 13-14, 16-22 and 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Warkentin et al. (U.S. Patent No. 6,824,512).

1. As per claim1, Warkentin teaches a medication storage, therapy, and consumption management system, comprising:

-an implantable device configured to implantably electrically monitor fluid retention **(Warkentin: col. 10, 66, to col. 11, 12)**;

-an external, non-ambulatory pill-dispensing containment unit configured to accessibly house diuretic medication, the containment unit including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication **(Warkentin: figures 4A-4C)**;

-a health management host system coupled to the containment unit in a manner that allows data transmission **(Warkentin: col. 12, 21-38)**;

-said containment unit including communications and control system that records and transmits data relating to a medication event, the medication event data including information related to the dispensing, said containment unit control system further providing for transmitting and receiving medication therapy data **(Warkentin: col. 10, 44-65)**;

-said health management host system configured to receive data related to the medication event, receive physiologic data, analyze the patient physiologic data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data **(Warkentin: col. 10, 66, to col. 11, 12 )**.

2. As per claim 2, the system of claim 1 is as described. Warkentin further teaches wherein the patient physiological data comprises weight, fluid retention data, data monitored by an implantable device and neuro-hormonal data **(Warkentin: col. 10, 66, to col. 11, 12)**.

3. As per claim 3, the system of claim 1 is as described. Warkentin further teaches wherein the containment unit is further configured to communicate wirelessly with said health management host system **(Warkentin: col. 6, 63 to col. 7, 6)**.

4. As per claim 4, the system of claim 1 is as described. Warkentin further teaches wherein the containment unit is configured with a display device to illustrate a medication therapy strategy **(Warkentin: col. 9, 19-63)**.

5. As per claim 5, the system of claim 4 is as described. Warkentin further teaches wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system **(Warkentin: col. 12, 21-38)**.

6. As per claim 6, the system of claim 1 is as described. Warkentin further teaches wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein **(Warkentin: 10, 44-65)**.

7. As per claim 8, the system of claim 1 is as described. Warkentin further teaches wherein said health management host system processes said data related to the medication event data and said patient physiological data, and in response thereto provides for the generation of an updated medication therapy regimen **(Warkentin: col. 10, 66, to col. 11, 12)**.

8. As per claim 9, Warkentin teaches an electronic patient health management system, comprising:

-an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data **(Warkentin: col. 10, 66, to col. 11, 12)**;

-an external, non-ambulatory, pill dispensing a medication therapy management device configured to accessibly house diuretic medication, the medication therapy management device including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication, the medication therapy management device being configure to store medication event data related to at least one of dispensing or patient consumption of medication, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the medication event data **(Warkentin: figures 4A-4C; col. 10, 44-65)**; and

-a patient wellness host system, communicatively coupled to the medication therapy management diagnostic device, configured to receive the processed data and use the processed data to generate a diuretic medication therapy regimen **(Warkentin: col. 12, 21-38)**.

9. As per claim 10, the system of claim 9 is as described. Warkentin further teaches wherein the medication therapy management diagnostic device is further configured to provide a reminder to a patient when it is time to take the medication **(Warkentin: 10, 44-65)**.

10. As per claim 13, the system of claim 9 is as described. Warkentin further teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via an Internet connection **(Warkentin: col. 12, 21-38)**.

11. As per claim 14, the system of claim 9 is as described. Warkentin further teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via a wireless communication link **(Warkentin: col. 6, 63 to col. 7, 6)**.

12. As per claim 16, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device **(Warkentin: col. 10, 66, to col. 11, 12)**.

13. As per claim 17, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises weight data **(Warkentin: col. 10, 66, to col. 11, 12)**.

14. As per claim 18, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data **(Warkentin: col. 10, 66, to col. 11, 12)**.

15. As per claim 19, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises renal function data **(Warkentin: col. 10, 66, to col. 11, 12)**.

16. As per claim 20, the system of claim 9 is as described. Warkentin further teaches further configured to process said data received in order to develop a therapeutic response **(Warkentin: col. 10, 66, to col. 11, 12)**.

17. As per claim 21, the system of claim 20 is as described. Warkentin further teaches wherein the developed therapeutic response comprises revising medication regime, maintaining current medication regime, and recommending a diet plan **(Warkentin: col. 10, 66, to col. 11, 12)**.

18. As per claim 22, the system of claim 9 is as described. Warkentin further teaches wherein the patient wellness host system is a computer, which comprises with a memory, a processor and a user interface **(Warkentin: col. 9, 2-18)**.

19. Claims 24-27 recite substantially similar limitations as those already addressed in claims 1-8, and, as such, are rejected for similar reasons as given above.

***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 7, 11, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warkentin et al. (U.S. Patent No. 6,824,512) in view of Mann et al. (U.S. Publication No. 2004/0147969).

22. As per claim 7, the system of claim 1 is as described. Warkentin does not explicitly teach wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level.

Mann, however, further teaches wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level **(Mann: para. 373)**.

One of ordinary skill in the art would have recognized that applying the known technique of Mann would have yielded predictable results and resulted in an improved system. It would have been recognized that applying the technique of Warkentin to the teachings of Mann would have yielded predictable results because the level of ordinary skill in the art demonstrated by the references applied shows the ability to incorporate such data processing features into similar systems.

23. As per claim 11, the system of claim 9 is as described. Warkentin does not explicitly teach comprising an external medical measurement device for measuring data related to at least one patient physiological health factor **(Mann: para. 19; 23)**.

Mann, however further teaches comprising an external medical measurement device for measuring data related to at least one patient physiological health factor **(Mann: para. 19; 23)**.

The motivation to combine the teachings is the same as claim 7.

24. As per claim 23, the system of claim 9 is as described. Warkentin does not explicitly teach wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level.

Mann, however, teaches wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level **(Mann: para. 349)**.

The motivation to combine the teachings is the same as claim 7.

25. Claim 28 recite substantially similar limitations as those already addressed in claim 11, and, as such, are rejected for similar reasons as given above.

***Response to Arguments***

26. Applicant's arguments with respect to claims 1-11, 13-14, and 16-28 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. R. R./
Examiner, Art Unit 3686
March 31, 2010

/Gerald J. O'Connor/
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